CLAIMS

What is claimed is:

Claim 1 - A double walled anchor for an intra-luminal stent-graft, comprising in combination:

an inner wall surrounding and defining a primary fluid conduit extending through said anchor;

an outer wall outboard from an exterior of said inner wall;

at least one void between said inner wall and said outer wall, said void adapted to be filled with fixation media; and

at least one of said walls having a contour generally defining an arm surrounding and defining at least one lateral fluid conduit joining with said primary fluid conduit.

Claim 2 - The double walled anchor of Claim 1 wherein said inner wall includes said contour generally defining said arm with said inner wall surrounding and defining said at least one lateral fluid conduit.

Claim 3 - The double walled anchor of Claim 2 wherein a portion of said outer wall is located outboard of said inner wall adjacent said arm with said lateral fluid conduit therein, said void extending between said outer wall and said inner wall within said arm.

Claim 4 - The double walled anchor of Claim 1 wherein fixation media is included within said at least one void.

Claim 5 - The double walled anchor of Claim 4 wherein said fixation media includes a gas.

Claim 6 - The double walled anchor of Claim 4 wherein said fixation media includes a liquid.

Claim 7 - The double walled anchor of Claim 4 wherein said fixation media includes a solid.

Claim 8 - The double walled anchor of Claim 4 wherein said fixation media includes a gel.

Claim 9 - The double walled anchor of Claim 4 wherein said fixation media includes a foam.

Claim 10 - The double walled anchor of Claim 1 wherein both said inner wall and said outer wall are formed from a material which is sufficiently flexible to allow said outer wall and said inner wall to be collapsed onto an elongate catheter beneath a sheath for intra-luminal implantation of said anchor.

Claim 11 - The double walled anchor of Claim 10 wherein both said inner wall and said outer wall are substantially inelastic.

Claim 12 - The double walled anchor of Claim 11 wherein said inner wall and said outer wall are each formed at least partially from parylene.

Claim 13 - The double walled anchor of Claim 12 wherein a liner is provided adjacent said inner wall and inboard of said inner wall, said liner including at least one opening adjacent said at least one lateral fluid conduit, such that fluid flow between said lateral fluid conduit and said primary fluid conduit can occur through said opening in said liner.

Claim 14 - The double walled anchor of Claim 12 wherein a liner is provided adjacent said inner wall and inboard of said inner wall, said liner being closed adjacent said at least one lateral fluid conduit, such that said liner blocks fluid flow between said lateral fluid conduit and said primary fluid conduit.

Claim 15 - The double walled anchor of Claim 1 wherein at least one interconnection is provided within said at least one void, said interconnection spanning said void between said inner wall and said outer wall, said at least one interconnection formed of a sufficiently inelastic material such that said interconnection controls expansion of said void when said void is filled with fixation media.

Claim 16 - The double walled anchor of Claim 15 wherein said at least one interconnection includes a plurality of quilting walls extending between said inner wall and said outer wall.

Claim 17 - The double walled anchor of Claim 15 wherein said at least one interconnection includes a plurality of quilting regions extending between said inner wall and said outer wall.

Claim 18 - The double walled anchor of Claim 1 wherein a substantially tubular graft is coupled to said anchor, said graft extending away from said anchor in a manner extending a length of said primary fluid conduit beyond said anchor and within said graft.

Claim 19 - The double walled anchor of Claim 18 wherein said graft includes an inner wall surrounding and defining said primary fluid conduit extending from said anchor and an outer wall outboard of said inner wall, said outer wall spaced from said inner wall by a void adapted to be filled with a fixation media.

Claim 20 - The double walled anchor of Claim 18 wherein said graft consists of a single wall surrounding and defining said primary fluid conduit extending from said anchor.

Claim 21 - The double walled anchor of Claim 1 wherein at least one radially expandable stent is located in a position circumferentially surrounding said arm surrounding and defining said at least one lateral fluid conduit, said stent having a first collapsed diameter and a second expanded diameter, said second expanded diameter having a greater diameter measurement than said first collapsed diameter, said stent adapted to be radially expanded to join said arm of said anchor to a lateral lumen near where the lateral lumen joins with a primary lumen within which said anchor is located, such that said anchor is at least partially held in place by said stent.

Claim 22 - A custom shaped anchor for an intra-luminal stent-graft, comprising in combination:

a first wall surrounding and defining a primary fluid conduit;

said primary fluid conduit including an inlet into said anchor and an outlet out of said anchor;

said first wall having a contour surrounding and defining at least one lateral fluid conduit joined with said primary fluid conduit within said first wall, such that fluids can pass between said primary fluid conduit and said lateral fluid conduit; and

said contour of said first wall having a particular geometry at least partially following a particular patient's luminal anatomy into which said anchor is adapted to be implanted.

Claim 23 - The custom shaped anchor of Claim 22 wherein said first wall has a contour surrounding and defining at least two lateral fluid conduits, said at least two lateral fluid conduits having a position relative to each other and a size which correspond with a particular patient's luminal anatomy into which said anchor is adapted to be implanted.

Claim 24 - The custom shaped anchor of Claim 22 wherein said first wall is an inner wall;

wherein said anchor includes an outer wall outboard from an exterior of said inner wall; and

wherein said anchor includes at least one void between said inner wall and said outer wall, said void adapted to be filled with a fixation media.

Claim 25 - The custom shaped anchor of Claim 24 wherein said inner wall includes said contour generally defining an arm with said inner wall surrounding and defining said at least one lateral fluid conduit.

Claim 26 - The custom shaped anchor of Claim 25 wherein at least one interconnection is provided within said at least one void, said interconnection spanning said void between said inner wall and said outer wall, said at least one interconnection formed of a sufficiently inelastic material such that said interconnection controls expansion of said void when said void is filled with fixation media.

Claim 27 - The custom shaped anchor of Claim 26 wherein said at least one interconnection includes a plurality of quilting walls extending between said inner wall

and said outer wall.

Claim 28 - The custom shaped anchor of Claim 26 wherein said at least one interconnection includes a plurality of quilting regions extending between said inner wall and said outer wall.

Claim 29 - The custom shaped anchor of Claim 22 wherein a substantially tubular graft is coupled to said anchor, said graft extending away from said anchor in a manner extending a length of said primary fluid conduit beyond said anchor and within said graft.

Claim 30 - The custom shaped anchor of Claim 29 wherein said graft includes an inner wall surrounding and defining said primary fluid conduit extending from said anchor and an outer wall outboard of said inner wall, said outer wall spaced from said inner wall by a void adapted to be filled with a fixation media.

Claim 31 - The custom shaped anchor of Claim 29 wherein said graft consists of a single wall surrounding and defining said primary fluid conduit extending from said anchor.

Claim 32 - The custom shaped anchor of Claim 22 wherein at least one radially expandable stent is located in a position circumferentially surrounding said arm surrounding and defining said at least one lateral fluid conduit, said stent having a first collapsed diameter and a second expanded diameter, said second expanded diameter having a greater diameter measurement than said first collapsed diameter, said stent adapted to be radially expanded to join said arm of said anchor to a lateral lumen near where the lateral lumen joins with a primary lumen within which said anchor is located, such that said anchor is at least partially held in place by said stent.

Claim 33 - A method of forming a double walled anchor for an intra-luminal stent-graft, the double walled anchor having an inner wall surrounding and defining a primary fluid conduit extending through said anchor, an outer wall outboard from an exterior of said inner wall, and at least one void between said inner wall and said outer wall, said

void adapted to be filled with fixation media, the steps including:

providing a sacrificial mandrel having a shape and size similar to the void of the double walled anchor;

forming a layer of anchor wall material on surfaces of the sacrificial mandrel; and

removing at least a portion of the sacrificial mandrel to form the void.

Claim 34 - The forming method of Claim 33 wherein said forming step includes the step of depositing the anchor wall material within a vacuum by vapor deposition.

Claim 35 - The forming method of Claim 34 wherein said depositing step includes the step of depositing parylene by vapor deposition within a vacuum.

Claim 36 - The forming method of Claim 33 wherein said forming step includes the step of dipping the sacrificial mandrel into a container with the anchor wall material therein.

Claim 37 - The forming method of Claim 33 wherein said forming step includes the step of spraying the anchor wall material onto the sacrificial mandrel.

Claim 38 - The forming method of Claim 33 wherein said removing step includes the step of dissolving the sacrificial mandrel.

Claim 39 - The forming method of Claim 33 wherein said removing step includes the step of chemically reacting the sacrificial mandrel with a reactant.

Claim 40 - The forming method of Claim 39 wherein said chemically reacting step includes the step of combusting the sacrificial mandrel with an oxidizer.

Claim 41 - The forming method of Claim 33 wherein said removing step includes the step of changing the phase of the sacrificial mandrel from a solid phase to a phase taken from the group consisting of a liquid phase and a gaseous phase.

Claim 42 - The forming method of Claim 33 wherein said providing a sacrificial mandrel step includes the step of positioning slots within the sacrificial mandrel which extend from an exterior surface of the sacrificial mandrel to an interior surface of the sacrificial mandrel, such that after said forming step and said removing step

interconnections are provided between the inner wall and the outer wall of the double walled anchor at locations corresponding with locations of the slots in the sacrificial mandrel.

Claim 43 - The forming method of Claim 33 wherein said providing a sacrificial mandrel step is followed by the steps including:

cutting the sacrificial mandrel into a plurality of separate pieces;

coating the separate pieces;

reassembling the separate pieces; and

continuing to said forming step, said forming step reconnecting the separate pieces together.

Claim 44 - The forming method of Claim 33 including the further step of attaching a liner inboard of the inner wall of the anchor after said forming step.

Claim 45 - A method of forming a custom shaped anchor for an intra-luminal stent-graft, the anchor having a first wall surrounding and defining a primary fluid conduit, said contour of said first wall having a particular geometry at least partially following a particular patient's luminal anatomy into which said anchor is adapted to be implanted, the steps of the forming method including:

providing at least one molding surface having a contour following a particular geometry of a particular patient's luminal anatomy;

forming the first wall of the anchor against the mold surface; and

removing the mold surface from the first wall.

Claim 46 - The custom forming method of Claim 45 wherein said providing step includes the steps of:

imaging at least a portion of the patient's luminal anatomy;

creating a data file corresponding to the patient's luminal anatomy;

building a patient luminal anatomy model from the data in the data file; and

constructing the molding surface from the model of said building step.

Claim 47 - The custom forming method of Claim 46 wherein said imaging step includes the step of using a computer tomography (CT) scanning apparatus.

Claim 48 - The custom forming method of Claim 46 wherein said imaging step includes the step of using an x-ray imaging device.

Claim 49 - The custom forming method of Claim 46 wherein said imaging step includes the step of using an ultrasound imaging device.

Claim 50 - The custom forming method of Claim 46 wherein said imaging step includes the step of using a magnetic resonance imaging (MRI) device.

Claim 51 - The custom forming method of Claim 45 wherein said providing step includes providing a sacrificial mandrel having a shape and size similar to a void between inner and outer walls of the anchor; and removing at least a portion of the sacrificial mandrel to form the void, such that a double walled anchor is formed having a void between the two walls thereof.

Claim 52 - The custom forming method of Claim 45 wherein said forming step includes the step of dipping the molding surface into material from which the first wall of the anchor is to be formed.

Claim 53 - The custom forming method of Claim 45 wherein said forming step includes the step of spraying material from which the first wall of the anchor is to be made against the molding surface.

Claim 54 - The custom forming method of Claim 45 wherein said forming step includes the step of locating the molding surface within a vacuum and depositing by vapor deposition material from which the first wall of the anchor is to be made against the molding surface.

Claim 55 - The custom forming method of Claim 54 wherein said depositing step includes the step of depositing parylene by vapor deposition against the molding surface.

Claim 56 - The custom forming method of Claim 51 wherein said removing step includes the step of dissolving the sacrificial mandrel.

Claim 57 - The custom forming method of Claim 51 wherein said removing step includes the step of chemically reacting the sacrificial mandrel with a reactant.

Claim 58 - The custom forming method of Claim 51 wherein said removing step includes the step of melting the sacrificial mandrel.

Claim 59 - A method for deploying a double walled anchor intra-luminally, the double walled anchor including an inner wall surrounding and defining a primary fluid conduit extending through said anchor, an outer wall outboard from an exterior of said inner wall, and at least one void between said inner wall and said outer wall, said void adapted to be filled with fixation media; the deployment method including the steps of:

collapsing the anchor onto a catheter;

advancing the catheter from a lumen insertion point to an implantation site for the anchor;

expanding the inner wall and the outer wall of the anchor away from the catheter to a desired position for the inner wall; and

filling the void between the inner wall and the outer wall with fixation media.

Claim 60 - The deployment method of Claim 59 including the further step of supporting the inner wall adjacent an inboard surface of the inner wall during said filling step, such that a position of the inner wall is not deflected inward during said filling step.

Claim 61 - The deploying method of Claim 60 wherein said supporting step includes the step of positioning a lumen shaper balloon inboard of the inner wall of the anchor during said filling step.

Claim 62 - The deploying method of Claim 61 wherein said expanding step includes the step of inflating the lumen shaper balloon inboard of the inner wall until the inner wall and the outer wall are expanded away from the catheter to the desired position for the inner wall, said lumen shaper balloon remaining inflated and adjacent the inner wall

during said filling step to provide support for the inner wall.

Claim 63 - The deploying method of Claim 59 wherein said filling step includes the steps of:

delivering fixation media into the void between the inner wall and the outer wall; and

expanding the outer wall away from the inner wall and away from the catheter to a desired position for the outer wall.

Claim 64 - The deploying method of Claim 63 including the further step of continuing said expanding step until said outer wall contacts a wall of the lumen at the implantation site for the anchor.

Claim 65 - The deploying method of Claim 59 including the further step of allowing the fixation media to set from a more fluid form to a less fluid form.

Claim 66 - The deployment method of Claim 59 including the further step of diverting fluid flow from passage through the lumen at the implantation site to a pathway through the catheter, at least during said expanding step and said filling step, such that fluid flow through the lumen continues.

Claim 67 - The deployment method of Claim 59 including the further step of providing the anchor with at least one of the walls having a contour generally defining an arm surrounding and defining at least one lateral fluid conduit joining with the primary fluid conduit.

Claim 68 - The deployment method of Claim 67 including the further step of providing a lumen shaper balloon having a deflated lesser diameter form and an inflated greater diameter form, said inflated greater diameter form having a contour at least partially matching a contour of the anchor adjacent the lateral conduit of the anchor, such that transition of the lumen shaper balloon from the deflated form to the inflated form during said expanding step causes the arm of the anchor adjacent the lateral conduit to be expanded into a lateral lumen extending from a primary lumen in which

the implantation site is located.

Claim 69 - The deployment method of Claim 68 including the further steps of:

positioning a radially expandable stent on the arm surrounding the lateral conduit of the anchor and expanding the radially expandable stent until said radially expandable stent assists in engaging the arm of the anchor with the lateral lumen adjacent the implantation site for the anchor.

Claim 70 - The deployment method of Claim 59 including the further step of coupling a graft to the anchor, the graft having a tubular form surrounding the primary fluid conduit and extending the primary fluid conduit beyond the anchor.

Claim 71 - The deployment method of Claim 70 wherein said coupling step precedes said collapsing step, such that said graft is coupled to the anchor before implantation thereof.

Claim 72 - The deployment method of Claim 71 including the further step of forming the graft together with the anchor before said collapsing step.

Claim 73 - The deployment method of Claim 71 including the further step of attaching the graft to the anchor before said implantation step.

Claim 74 - The deployment method of Claim 70 wherein said coupling step occurs after said advancing step, said coupling step including the step of attaching the graft to the anchor after the anchor has been located at the implantation site for the anchor.

Claim 75 - A double walled intra-luminal stent-graft, comprising in combination:

an inner wall surrounding and defining a primary fluid conduit extending through said stent-graft;

an outer wall outboard from an exterior of said inner wall;

at least one void between said inner wall and said outer wall, said void adapted to be filled with fixation media; and

wherein at least one interconnection is provided within said at least one void, said interconnection spanning said void between said inner wall and said outer wall.

Claim 76 - The double walled stent-graft of Claim 75 wherein said at least one interconnection is formed of a sufficiently inelastic material such that said interconnection controls expansion of said void when said void is filled with fixation media.

Claim 77 - The double walled stent-graft of Claim 76 wherein said at least one interconnection includes a plurality of quilting walls extending between said inner wall and said outer wall.

Claim 78 - The double walled stent-graft of Claim 76 wherein said at least one interconnection includes a plurality of quilting regions extending between said inner wall and said outer wall.

Claim 79 - The double walled stent-graft of Claim 75 further including an anchor having an inner anchor wall surrounding and defining the primary fluid conduit adjacent an end of the stent-graft, with the primary fluid conduit extending through said anchor; and

said inner anchor wall having a contour in the form of an arm surrounding and defining at least one lateral fluid conduit joining with said primary fluid conduit within said anchor.

Claim 80 - The double walled stent-graft of Claim 79 wherein said anchor includes an outer anchor wall outboard from an exterior of said inner anchor wall; and

at least one void between said inner anchor wall and said outer anchor wall, said anchor void adapted to be filled with fixation media.

Claim 81 - The double walled stent-graft of Claim 80 wherein said inner anchor wall is formed with said anchor wall of said stent-graft and said outer anchor wall is formed with said outer wall of said stent-graft, such that said anchor and said stent-graft form a single unit.

Claim 82 - The double walled stent-graft of Claim 80 further including a means to couple said anchor to said stent-graft.

Claim 83 - The double walled stent-graft of Claim 75 wherein said at least one connection divides said void into multiple separate chambers, said separate chambers separately fillable with the fixation media.

Claim 84 - The double walled stent-graft of Claim 83 wherein said multiple chambers of said void are shaped as toroids surrounding said primary fluid conduit.

Claim 85 - An inflatable lumen shaper balloon for expanding, positioning and supporting an anchor for an intra-luminal stent-graft during expansion thereof, the inflatable lumen shaper balloon comprising in combination:

an exterior wall defining a fillable bladder;

at least one arm in the exterior wall extending away from other portions of the exterior wall;

means to attach said exterior wall to an intra-luminal delivery catheter; and

means to inflate said bladder.

Claim 86 - The balloon of Claim 85 wherein a contour of said exterior wall is shaped to at least partially match a contour of an inner wall of a double walled anchor.

Claim 87 - The balloon of Claim 86 wherein the double walled anchor includes at least one arm extending away from a primary fluid conduit passing through the anchor, said balloon including a balloon arm sized and positioned to be located within the arm of the anchor.

Claim 88 - The balloon of Claim 87 wherein said balloon arm is longer than the anchor arm, such that said balloon arm extends at least partially out of the anchor arm.

Claim 89 - The balloon of Claim 88 wherein said balloon arm has a position and location which correspond with a lumen anatomy of a particular patient.

Claim 90 - The balloon of Claim 85 wherein a knob is included at the end of said at least one arm, said knob having a greater inflated diameter than portions of said arm adjacent said knob.

Claim 91 - A catheter for delivery of a stent-graft intra-luminally, comprising in combination:

a guide wire;

a central conduit extending along a stent-graft delivery portion of said catheter, said central conduit including a bypass inlet at a first end of said central conduit closer to said guide wire and a bypass outlet located at a side of said central conduit further from said guide wire than said bypass inlet;

a balloon inflation fluid pathway passing through an interior of said catheter to a balloon inflation fluid port in said stent-graft delivery portion of said catheter; and

a fixation media delivery pathway extending through said catheter to a media delivery port adjacent said stent-graft delivery portion of said catheter.

Claim 92 - The catheter of Claim 91 further including a seal balloon between said bypass inlet and said bypass outlet, said seal balloon adapted to be expanded to substantially occlude a lumen in which the catheter is located, such that fluid can primarily only pass through the lumen by passing through said central conduit through said bypass inlet and said bypass outlet.

Claim 93 - The catheter of Claim 91 wherein said catheter is formed entirely of material which is sufficiently flexible to allow said catheter to pass intra-luminally from a femeral artery of a human patient, up to an aorta of the human patient.

Claim 94 - The catheter of Claim 91 wherein at least a portion of said catheter is formed of a radiopaque material.

Claim 95 - The catheter of Claim 94 wherein said catheter includes radiopaque material selectively located at positions axially and radially spaced from each other upon said catheter, such that a position and orientation of said catheter can be determined when said catheter is viewed through a fluoroscope or other radiopacity sensitive imaging device.

Claim 96 - The catheter of Claim 95 further including a sheath adapted to be removably placed over a stent-graft delivery portion of said catheter, said sheath having a diameter at least as great as a diameter of said stent-graft support region of said catheter plus a thickness of a collapsed lumen shaper balloon and a collapsed stent-graft upon said catheter.

Claim 97 - The catheter of Claim 91 wherein said fixation media delivery pathway is in the form of a tube.